OCT 0 7 2008

K081666

VII. SECTION 10 - 510(K) SUMMARY

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. **Applicant's Name and Address**

Astra Tech Inc.
25 First Street
Cambridge, Massachusetts 02141
Telephone Number: 617-661-9799
Fax Number: 617-661-9063
Contact Person: Franklin Uyleman
Manager of Quality and Regulatory Affairs

2. **Name of Device**

Trade Name: Atlantis™ Abutment for Astra Tech OsseoSpeed 3.0 Implant System
Common Name: Endosseous dental implant abutment
Classification Name: Endosseous dental implant abutment
21 CFR 872.3630 Product code NHA

3. **Legally Marketed Device to which Equivalence is claimed (Predicate Device)**

Manufacturer	Device	510(k) Number
Astra Tech Inc., (formerly Atlantis Components Inc.)	-Atlantis Abutment for Astra Implant	K070833
Astra Tech AB	-OsseoSpeed™ Narrow	K080396

4. **Description of the Device**

The devices covered in this submission are abutments which are placed into the dental implant to provide support for a prosthetic restoration. The subject abutments are indicated for cemented restorations.

4. **Description of the Device (continued)**

The **Atlantis™ Abutments for Astra Tech OsseoSpeed 3.0 Implant System** and abutment screws are made from Titanium grade Ti-6A1-4V ELI (Meets ASTM Standard F-136). The abutment is placed over the implant shoulder and is mounted into the implant with a screw. The abutments are compatible with Astra's 3.0 mm OsseoSpeed™ Implants.

5. **Intended Use of the Device**

The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic reconstruction. The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the maxillary lateral incisors and mandibular lateral and central incisors. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

6. **Basis for Substantial Equivalence**

The **Atlantis™ Abutments for Astra OsseoSpeed 3.0 Implants** are substantially equivalent in intended use, material, design and performance to the Atlantis Abutments for Astra Implants cleared under K070833 and for the Astra Tech OsseoSpeed ™ Narrow Implants cleared under K080396.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 7 2008

Astra Tech, Incorporated
C/O Ms. Betsy A. Brown
Consultant
B.A. Brown & Associates
8994 Tamaroa Terrace
Skokie, Illinois 60076

Re: K081666
Trade/Device Name: Atlantis™ Abutment for Astra Tech OsseoSpeed 3.0 Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 24, 2008
Received: September 26, 2008

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M Samuels-Lev, MD for

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Pre-market Notification
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Indications for Use

510(k) Number (if Known)_____

Device Name: Atlantis ™ Abutment for Astra Tech OsseoSpeed 3.0 Implant System

Indication for Use:

The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the maxillary lateral incisors and mandibular lateral and central incisors. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.
This device is compatible with the Astra Tech OsseoSpeed 3.0 mm Implant.

Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.
Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 SubpartD) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081666